## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Attorney Docket No. 00-388-A)

In re the Application of:	)
Nolan et al.	) Examiner: S.J. Shararel
Application No.: 09/851,743	) Group Art Unit: 1617
Filing Date: May 9, 2001	) Confirmation No: 4067
For: Methods for Testing Compounds Useful In Treating Diabetic Complications	) ) )

## RESPONSE TO THE OFFICE ACTION MAILED APRIL 7, 2006

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Responsive to the Official Action, mailed April 7, 2006, Applicants respectfully request reconsideration of the pending claims in light of the following remarks and amendments. Amendments begin on page 2 of this response. Remarks begin on page 5 of this response.

## **Status of the Claims in this Application**

Claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31 and 33-35 are pending in the application. Claims 1 and 13 have been amended and new claims 36-46 have been added. The amendments are supported throughout the specification and claims as originally filed, and thus do not constitute new matter.

## **AMENDMENTS TO THE CLAIMS**

Please amend the following claims:

- 1. (Previously Presented) A method for identifying a compound that improves treatment of wounds to dermis or epidermis in a diabetic animal, the method comprising:
  - a) producing a wound in the dermis or epidermis of the diabetic animal;
- b) exposing the wound to an aldose reductase inhibitor compound by topical application of the compound to the wound;
- c) comparing wound healing in the presence of the compound to wound healing in the absence of the compound; and
- d) identifying a compound that improves treatment of wounds to skin or another external body surface in the animal if the wound contracts more in a shorter period of time when treated in the presence of the compound than when the wound is treated in the absence of the compound.
  - 2. (Previously presented) The method of Claim 1, further comprising the step of:
- e) comparing wound healing in the presence of a test compound with wound healing in the presence of a control aldose reductase inhibitor, wherein the test compound is identified as a compound that improves treatment of wounds to or another external body surface in an animal if the wound heals at least as rapidly, completely or less painfully in the presence of the test compound as in the presence of the control aldose reductase inhibitor.
  - 3. (Original) The method of Claim 1, wherein the animal is a mammal.
  - 4. (Original) The method of Claim 1, wherein the animal is a human.
  - 5. (Canceled)
  - 6. (Original) The method of Claim 1, wherein the wound is to skin on an animal.
  - 7. (Original) The method of Claim 1, wherein the wound is produced by punch biopsy.
- 8. (Withdrawn) A method for treating wounds in a diabetic animal, comprising administering to the animal a compound that improves treatment of wounds to skin or another external body

surfaces in an animal in an amount effective to improve wound healing in the animal, wherein the compound is identified according to the method of claim 1.

- 9. (Withdrawn) The method of claim 8, wherein the animal is a mammal.
- 10. (Withdrawn) The method of claim 8, where in the animal is a human.
- 11. (Withdrawn) The method of claim 8, where in the human is a diabetic.
- 12. (Withdrawn) The method of claim 1, wherein the test compound is an aldose reductase inhibitor.
- 13. (Previously Presented) A method for identifying a compound that improves diabetic neuropathy or neurological disorders associated with diabetes, the method comprising:
  - a) producing a wound in the dermis or epidermis of a diabetic animal;
- b) exposing the wound to an aldose reductase inhibitor compound by topical application of the compound to the wound;
- c) comparing wound healing in the presence of the compound to wound healing in the absence of the compound; and
- d) identifying a compound that improves diabetic neuropathy or neurological disorders associated with diabetes if the wound contracts more in a shorter period of time when treated in the presence of the compound than when the wound is treated in the absence of the compound.
  - 14. (Previously Presented) The method of Claim 13, further comprising:
- e) comparing wound healing in the presence of a test compound with wound healing in the presence of a control aldose reductase inhibitor, wherein the test compound is identified as a compound that improves diabetic neuropathy or neurological disorders associated with diabetes if the wound heals at least as rapidly, completely or less painfully in the presence of the compound as in the presence of the control aldose reductase inhibitor.
  - 15. (Original) The method of Claim 13, wherein the animal is a mammal.
  - 16. (Original) The method of Claim 13, wherein the animal is a human.
  - 17. (Canceled)

- 18. (Original) The method of Claim 13, wherein the wound is to skin on an animal.
- 19. (Previously Presented) The method of Claim 13, wherein the wound is produced by punch biopsy.
- 20. (Withdrawn) A method for treating diabetic neuropathy or neurological disorders associated with diabetes in a diabetic animal, comprising administering to the animal compound that improves treatment of wounds to skin or another external body surfaces in an animal in an amount effective to improve diabetic neuropathy or neurological disorders associated with diabetes in the animal, wherein the compound is identified according to the method of claim 13.
  - 21. (Withdrawn) The method of claim 20, where the animal is a mammal.
  - 22. (Withdrawn) The method of claim 20, where the animal is a human.
  - 23. (Withdrawn) The method of claim 20, where the human is a diabetic
- 24. (Withdrawn) The method of claim 13, wherein the test compound is an aldose reductase inhibitor.
  - 25. (Original) The method of Claim 2, wherein the animal is a mammal.
  - 26. (Original) The method of Claim 2, wherein the animal is a human.
  - 27. (Canceled)
  - 28. (Original) The method of Claim 2, wherein the wound is to skin on an animal.
  - 29. (Original) The method of Claim 2, wherein the wound is produced by punch biopsy.
  - 30. (Original) The method of Claim 14, wherein the animal is a mammal.
  - 31. (Original) The method of Claim 14, wherein the animal is a human.
  - 32. (Canceled)
  - 33. (Original) The method of 14, wherein the wound is to skin on an animal.
  - 34. (Original) The method of 14, wherein the wound is produced by punch biopsy.
- 35. (Previously Presented) A method of healing or treating wounds using an aldose reductase inhibitor identified by the method of claims 1 or 13.

- 36. (New) A method for identifying a compound that improves treatment of wounds to dermis or epidermis in a diabetic animal, the method comprising:
  - a) producing a wound in the dermis or epidermis of the diabetic animal;
  - b) exposing the wound to an aldose reductase inhibitor compound by topical application of the compound to the wound;
  - c) calculating the wound size and degree of wound contraction as:
  - {(size of wound at day 0 size of wound at day X)/ size of wound at day 0 + size of wound at day 0} X 100;
  - d) comparing wound healing in the presence of the compound to wound healing in the absence of the compound; and
  - e) identifying a compound that improves treatment of wounds to skin or another external body surface in the animal if the wound contracts more in a shorter period of time when treated in the presence of the compound than when the wound is treated in the absence of the compound.
  - 37. (New) The method of Claim 37, further comprising the step of:
    - f) comparing wound healing in the presence of a test compound with wound healing in the presence of a control aldose reductase inhibitor, wherein the test compound is identified as a compound that improves treatment of wounds to or another external body surface in an animal if the wound heals at least as rapidly, completely or less painfully in the presence of the test compound as in the presence of the control aldose reductase inhibitor.
  - 38. (New) The method of claim 36, where the animal is a mammal.
  - 39. (New) The method of claim 36, where the animal is a human.
  - 40. (New) The method of Claim 36, wherein the wound is produced by punch biopsy.
- 41. (New) A method for identifying a compound that improves diabetic neuropathy or neurological disorders associated with diabetes, the method comprising:
  - a) producing a wound in the dermis or epidermis of a diabetic animal;

- b) exposing the wound to an aldose reductase inhibitor compound by topical application of the compound to the wound;
- c) calculating the wound size and degree of wound contraction as:

{(size of wound at day 0 – size of wound at day X)/ size of wound at day 0} X 100;

- d) comparing wound healing in the presence of the compound to wound healing in the absence of the compound; and
- e) identifying a compound that improves diabetic neuropathy or neurological disorders associated with diabetes if the wound contracts more in a shorter period of time when treated in the presence of the compound than when the wound is treated in the absence of the compound.
- 42. (New) The method of Claim 41, further comprising:
- f) comparing wound healing in the presence of a test compound with wound healing in the presence of a control aldose reductase inhibitor, wherein the test compound is identified as a compound that improves diabetic neuropathy or neurological disorders associated with diabetes if the wound heals at least as rapidly, completely or less painfully in the presence of the compound as in the presence of the control aldose reductase inhibitor.
  - 43. (New) The method of claim 41, where the animal is a mammal.
  - 44. (New) The method of claim 41, where the animal is a human.
  - 45. (New) The method of Claim 41, wherein the wound is produced by punch biopsy.
- 46. (New) A method of healing or treating wounds using an aldose reductase inhibitor identified by the method of claims 36 or 41.